IS 6468 (1989): Thoracic Surgery Instruments - Trocar, Empyema, Nelson's Pattern [MHD 6: Thoracic and Cardiovascular Surgery Instruments]

BLANK PAGE

Indian Standard

(Reaffirmed 2005)

THORACIC SURGERY INSTRUMENTS— TROCAR, EMPYEMA, NELSON'S PATTERN— SPECIFICATION

(First Revision)

भारतीय मानक

ट्रोकार पुसुसावरणी अन्तराल शोध, नेलसन नमूने के — विशिष्टि

(पहला पुनरीक्षण)

UDC 615·472·3 : 617·54

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

July 1990

Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1972. In this revision, tolerances on various dimensions have been specified, requirements of the performance test have been altered, load closure test and an additional test for flexibility have been incorporated and the clauses on surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

THORACIC SURGERY INSTRUMENTS— TROCAR, EMPYEMA, NELSON'S PATTERN— SPECIFICATION

(First Revision)

1 SCOPE

This standard prescribes requirements and tests for Nelson's pattern empyema trocars used in thoracic surgery.

2 REFERENCES

2.1 The Indian Standards listed below are necessary adjuncts to this standard:

IS No.	*Title*
1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials : Part 1 HV 5 to HV 100 (*second revision*)
1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 Stainless and heat-resisting steels (*second revision*)
4905 : 1968	Methods for random sampling
6603 : 1972	Specification for stainless steel bars and flats
7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIALS

3.1 Trocar Shank and Handle

The trocar shank and handle shall be made of stainless steel conforming to Designation 30Cr13 or 40Cr13 of IS 6603 : 1972.

3.2 Cannula

The cannula shall be made of X04Cr19Ni9 or X07Cr18Ni9 of IS 1570 (Part 5) : 1985.

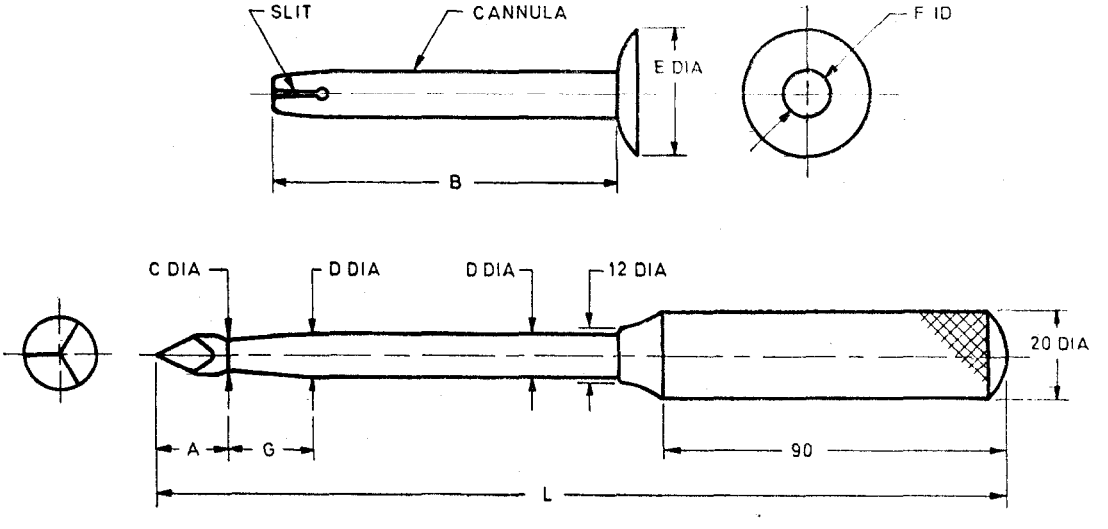
4 SHAPE AND DIMENSIONS

4.1 The shape and dimension of the instrument shall be as shown in Fig. 1.

4.2 Tolerances

Tolerances on various dimensions shall be as given below:

- ±0·05 mm on dimensions up to 2·0 mm;
- ±0·1 mm on dimensions above 2·0 mm and up to 5·0 mm;
- ±0·2 mm on dimensions above 5·0 mm and up to 20·0 mm;
- ±0·5 mm on dimensions above 20·0 mm and up to 50·0 mm;
- ±1·0 mm on dimensions above 50·0 mm and up to 100·0 mm;
- ±2·0 mm on dimensions above 100·0 mm.



Size	*L*	*A*	*B*	*C*	*D*	*E*	*F*	*G*
Small	185	16	70	5	6·5	24	7·3	14
Medium	190	17	75	6	8·0	26	8·7	17
Large	195	18	80	7	10·0	28	10·7	20

All dimensions in millimetres.

FIG. 1 TROCAR, EMPYEMA, NELSON'S PATTERN

5 HEAT TREATMENT

5.1 The trocar tip shall be hardened and tempered to 400 to 500 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

6 WORKMANSHIP

6.1 The trocar may be of one-piece or two-piece construction. In case of two-piece construction, the shank shall be attached securely and permanently to the handle.

6.2 The handle shall be knurled.

6.3 The trocar point shall be central and sharp. The cannula shall snugly fit on the trocar. The tip of the cannula shall be sprung in to snap on the tapered portion of the neck of the trocar. The trocar shall be capable of fitting into the cannula easily and shall be removable without undue force required to pull it out.

7 SURFACE CONDITION

7.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

7.2 Surface Finish

The surface finish of the instrument shall be reflection-reducing, for example, satin finish, matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding, brushing, electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and should reduce glare.

7.3 Passivation and Final Treatment

The instruments shall, unless the metallurgical characteristics of the instrument (for example the presence of brazed or soldered joints) render it inappropriate, be treated by a suitable passivation process, for example by electropolishing or by treatment with 10 percent (*v*/*v*) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

8 TESTS

8.1 Performance Test

8.1.1 When the trocar is rotated on a V-block, the tip shall remain at one point.

8.1.2 The trocar with the cannula on shall be made to pierce through a piece of soft wood, 6 mm thick. The instrument shall do this easily and rapidly and in so doing, the point and the cutting edges shall not become blunt or distorted.

8.1.3 The trocar with the cannula on shall be made to pierce through a piece of leather, 3 mm thick, soaked in water for 2 hours. The instrument shall do this easily and rapidly and in so doing the point and the cutting edges shall not become blunt or distorted.

8.2 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975.

9 MARKING AND PACKING

9.1 The instruments shall be legibly and indelibly marked with the indication of the source of manufacture, the words 'stainless steel' or letters 'ss'; and the country of manufacture.

9.2 After protecting the trocar point by a corrosion inhibiting plastic coating, the instruments shall be individually wrapped in a suitable cushioning material like folded tissue paper. Each instrument shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

9.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

9.3 The packages shall be marked with the name and size of the instrument; the indication of the source of manufacture, the words 'stainless steel'; and the country of manufacture.

10 SAMPLING

10.1 The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A
(*Clause* 10.1)

SAMPLING OF TROCAR, EMPYEMA, NELSON'S PATTERN

A-1 LOT

In any consignment, all the instruments of the same size, produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling
(*Clauses* A-2, A-3.1 *and* A-3.2)

Lot Size (1)	Sample Size (2)	Sub sample Size (3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure randomness of selection, procedures given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual). An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness, performance and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification, if none of the instruments in the sub-sample fails in any of these tests.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Revision of Indian Standards

Indian Standards are reviewed periodically and revised, when necessary and amendments, if any, are issued from time to time. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition. Comments on this Indian Standard may be sent to BIS giving the following reference:

Doc : No. MHD 6 (2096)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices:	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002	331 01 31 331 13 75
Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola, CALCUTTA 700054	37 86 62
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	2 18 43
Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113	41 29 16
Western : Manakalaya, E9 MIDC, Marol, Andheri (East), BOMBAY 400093	6 32 92 95

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR. PATNA. TRIVANDRUM.

Printed at Printrade, New Delhi, India